K080791

SENORX

APR 30 2008

7. 510(K) SUMMARY

Date prepared	March 14, 2008
Name	SenoRx, Inc. 11 Columbia Aliso Viejo, CA 92656 T. 949.362.4800; F. 949.362.0300
Contact person	Eben Gordon Vice President, RA/QA SenoRx, Inc. T. 949.362.4800; F. 949.362.0300
Device name	Contura MLB Source Applicator for Brachytherapy
Common name	Multi-lumen balloon source applicator
Classification name	Remote controlled radionuclide source applicator
Classification regulation	21 CFR 892.5700; 90 JAQ
Predicate device	SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy (K071229)
Description	The Contura MLB applicator consists of a multi-lumen catheter connected to an inflatable spherical balloon that can be attached to commercially available High Dose Rate remote afterloader equipment for passage of the radiation source delivery wire. Five radiation source wire lumens are provided; one central lumen located along the long axis of the applicator and four curved lumens symmetrically offset from the central lumen. The balloon is inflated to a 4 or 5 cm spherical shape by a controlled volume injection of physiological saline to approximately 33 or 58 ml, respectively.
Indications for use	The Contura Multi-Lumen Balloon Source Applicator for Brachytherapy is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.
Summary of substantial equivalence	The device design, materials, processes, etc. have not been changed with this application. The modification is to a warning only, therefore, the Contura Multi-Lumen Balloon Source Applicator as described in this submission is substantially equivalent to the predicate device.

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K080791 Third Party Organization: Regulatory Technology Services

Third Party's Primary Reviewer(s): Mark Job

ODE/OIVD Division: DRAAD Branch/Team: RADB

Section 2 – 510(k) Decision

Third party recommendation: SE ✓ NSE ____ Other (specify): ____

ODE/OIVD final decision: SE ✓ NSE ____ Other (specify): ____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	✓		
b. Extent of pre-submission consultation with ODE/OIVD division	✓		
c. Organization and format of review documentation	✓		
d. Determination of 510(k) administrative completeness (screening review)	✓		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	✓		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	✓		
g. Rationale for conclusions and recommendation		✓	
h. Use of guidance documents and standards	N/A		
i. Resolution of 510(k) deficiencies and FDA requests for additional information	✓		
j. Scope of reviewer expertise and use of consulting reviewers	✓		
k. Other (specify):			

Comments (explanation of ratings/issues): ____

Section 4 – ODE/OIVD Assessor Information

Assessed by: R. Phillips Date: 4/21/08 Tel. No.: 240-276-3666

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2008

SenoRx, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1393 25th Street NW
BUFFALO MN 55313

Re: K080791
Trade/Device Name: Contura Multi-Lumen Balloon Source Applicator for Brachytherapy
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: April 14, 2008
Received: April 15, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of the Contura Multi-Lumen Balloon Source Applicator for Brachytherapy as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

The Warning must be presented within a black box, and the font should be bold and the same size as any surrounding text. The Warning should be the first item in your list of warnings.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6. INDICATIONS FOR USE

510(k) Number (if known): K080791

Device Name: Contura Multi-Lumen Balloon Source Applicator for Brachytherapy

Indications for Use:

The Contura Multi-Lumen Balloon Source Applicator for Brachytherapy is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

Prescription Use ___X___ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080791

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